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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/918,127	07/30/2001	William J. Curatolo	PC10754AJTJ	1383

7590 07/28/2005

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/918,127	CURATOLO ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-99* is/are pending in the application.

4a) Of the above claim(s) *11-16 and 19-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,17,18 and 35-99* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *06/27/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

Examiner acknowledges receipt of request for continued examination under 37 CFR 1.114, IDS, request for extension of time, amendment and remarks filed 06/27/05. Claims 1-96 and new claims 97-99 are pending. Claims 11-16 and 19-34 are withdrawn from consideration.

Claim Rejections - 35 USC § 102

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 2-10, 17, 18, 35-51, 56-86 and 88 rejected under 35 U.S.C. 102(b) as being anticipated by Sikorski (WO 99/14204 cited by applicants in the disclosure and on the IDS filed 07/30/01).

Sikorski teaches a composition comprising cholesteryl ester transfer protein (CETP) inhibitor (page 4, line 30 to page 12 and line 19) and one or more non-toxic pharmaceutically acceptable carriers (page 80, line 4). On page 84, lines 27-29, Sikorski teach that CETP inhibitors are formulated as dispersions in hydroxypropylmethyl cellulose. Solutions and suspensions of the formulation can be prepared from sterile powders (page 84, lines 32 and 33). The active compound, which is the cholesteryl ester transfer protein inhibitor can be combined with one or more adjuvants and cellulose alkyl esters and polyvinylpyrrolidone are examples (page 84, lines 16-32). The formulation of Sikorski can be administered orally, intravascularly, intraperitoneally, subcutaneously, intramuscularly, topically (page 80, lines 11-14) and also to

the eye (page 84, lines 8-15). The compounds of Sikorski, the CETP's, are useful for human treatment, veterinary treatment, exotic and farm animal treatment (mammals, rodents, horses, dogs and cats) and the CETP's are useful in the treatment of dyslipidemia, coronary artery disease, atherosclerosis and coronary artery diseases (page 6, lines 2-20). Sikorski also discloses how to measure CETP activity *in Vitro* (page 71, line 14 to page 72 line 21) and inhibition of CETP activity is also tested *in Vivo* (page 72, line 23 to page 74 line 13).

Since pharmaceutical formulation of the CETP's can be in the form of tablet, capsule, suspension or liquid, the gastrointestinal tract is a use environment. Instant claims 35- 48 and 56-73 recite the properties of the pharmaceutical composition and how the composition is made instant claim 86 is not critical in a composition claim.

Sikorski meets the limitations of the claims.

4. Applicant's arguments filed 06/27/05 have been fully considered but they are not persuasive.

Regarding applicants' argument that Sikorski does not disclose solid amorphous dispersions as required by applicants, it is noted that Sikorski discloses a composition comprising cholesteryl ester transfer protein (CETP) inhibitor (page 4, line 30 to page 12 line 19). Furthermore, on page 84, lines 27-29, Sikorski discloses that active compound may be dispersed in hydroxypropylmethyl cellulose. Although applicants contend that a single disclosure of dispersion by Sikorski may not constitute a disclosure for dispersion, Sikorski as acknowledged by applicants discloses dispersion. Sikorski uses the term dispersion. Applicants' argument that Sikorski is a controlled release formulation, which does not generally increase the maximum concentration and/or bioavailability of a poorly soluble drug has been considered but that

argument is not persuasive because the instant claims are directed to compositions that contain solid dispersions of low-solubility drugs in/with concentration enhancing polymers. The concentration enhancing polymers are as recited in claim 2 and hydroxypropylmethyl cellulose is one of the recited polymers. Sikorsky discloses a low-solubility drug, CETP dispersed in hydroxypropylmethyl cellulose. Powder is amorphous and the Remington article provided does not state that powders are not amorphous. The amorphous side of the Remington teaching reference is valid to Examiner's position. The article provided discusses the means of producing powders and in first paragraph, left column, powders are categorized as finely divided solid materials. As for controlled release nature of Sikorski as analyzed by applicants, it is respectfully noted that the examined claims do not exclude controlled release formulations and controlled release is determined by the matrix excipients that make up the formulation. The claims are not directed to process of formulating the composition and the claims are not product by process claims so that the process of making the formulation would provide a product that is structurally different from the composition of Sikorski. PRODUCT-BY-PROCESS CLAIMS ARE NOT LIMITED TO THE MANIPULATIONS OF THE RECITED STEPS, ONLY THE STRUCTURE IMPLIED BY THE STEPS.

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 1, 52-55, 87 and 89-99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sikorski (WO 99/14204).

Sikorski clearly teaches the teaches the composition of the instant claims except that Sikorski does not teach the concentration enhancing polymers recited in claims 52-55. Regarding claim 87 spray drying technique for the preparation of the formulation is recited, it is respectfully submitted that spray drying is one of the processes of forming tablets. It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the composition of Sikorski that comprises CETP and hydroxypropymethyl cellulose. One having ordinary skill in the art would have been motivated to substitute one concentration-enhancing polymer with another with the expectation that the concentration of the CETP will be enhanced.

Sikorski has been discussed. Sikorski's composition is administered to subject in need thereof to treat conditions treatable with CETP's. The conditions recited in claims 89-96 are all conditions that are treatable with CETP. Spray drying is a known method in the art for producing dispersion or tablets or granules or pellets. Sikorski does not disclose the polymers recited in claim 1. One polymer can be substituted for another. And it is known in the art that hydroxypropylmethyl-cellulose, hydroxypropylmethylcellulose phthalate, hydroxypropylmethylcellulose acetate succinate, hydroxypropylmethylcellulose acetate phthalate, cellulose acetate phthalate, cellulose acetate trimellitate, polyvinyl pyrrolidone, polyvinyl alcohol, and copolymers of polyvinyl pyrrolidone and polyvinyl alcohol are equivalent as dispersion polymers (Appel et al. US 6,706,283, claim 30 is a teaching reference).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to disperse CETP in hydroxypropylmethyl cellulose according to Sikorski. One having ordinary skill in the art would have been motivated to substitute

hydroxypropylmethyl cellulose with hydroxypropylmethylcellulose phthalate, hydroxypropylmethylcellulose acetate succinate, hydroxypropylmethylcellulose acetate phthalate, cellulose acetate phthalate, cellulose acetate trimellitate, polyvinyl pyrrolidone, polyvinyl alcohol, or copolymers of polyvinyl pyrrolidone and polyvinyl alcohol with the expectation of dispersing CETP.

A teaching reference is a prior art that discloses what is known in the art. The teaching reference does not have to be cited as a prior art in combination with primary reference if that reference is relied upon to show what is known in the art.

New claims 97-99 are included with the rejection under 35 USC 103.

7. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600